REMARKS

SPECIFICATION

Applicants have amended the specification to include the information in the originally filed Figure 10. Support for the amendment to the specification can be found in Figure 10 as originally filed. Accordingly, these changes do not involve new matter and entry is respectfully requested.

DRAWINGS

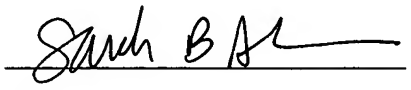
Applicants submit a replacement sheet for Figure 10. The originally-filed Figure 10 contains errors, i.e., the y-axis of Figures 10A and 10B should indicate 0, 200, 400 and 600.

Applicants submit a copy of originally-filed Figure 10, annotated with markings to indicate the changes in the figure (attached herein as Exhibit A). Applicants also provide a replacement sheet of Figure 10 which now indicates the correction (attached herein as Exhibit B).

The changes contained in the replacement sheet do not introduce new matter. Support for the changes can be found in the originally-filed specification at page 28, lines 14-17 and lines 19-22. Applicants provide a copy of page 28 (Exhibit C).

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, Applicants hereby authorize the Patent Office to charge the amount of any such fee to Deposit Account No. 50-0306.

Respectfully submitted,



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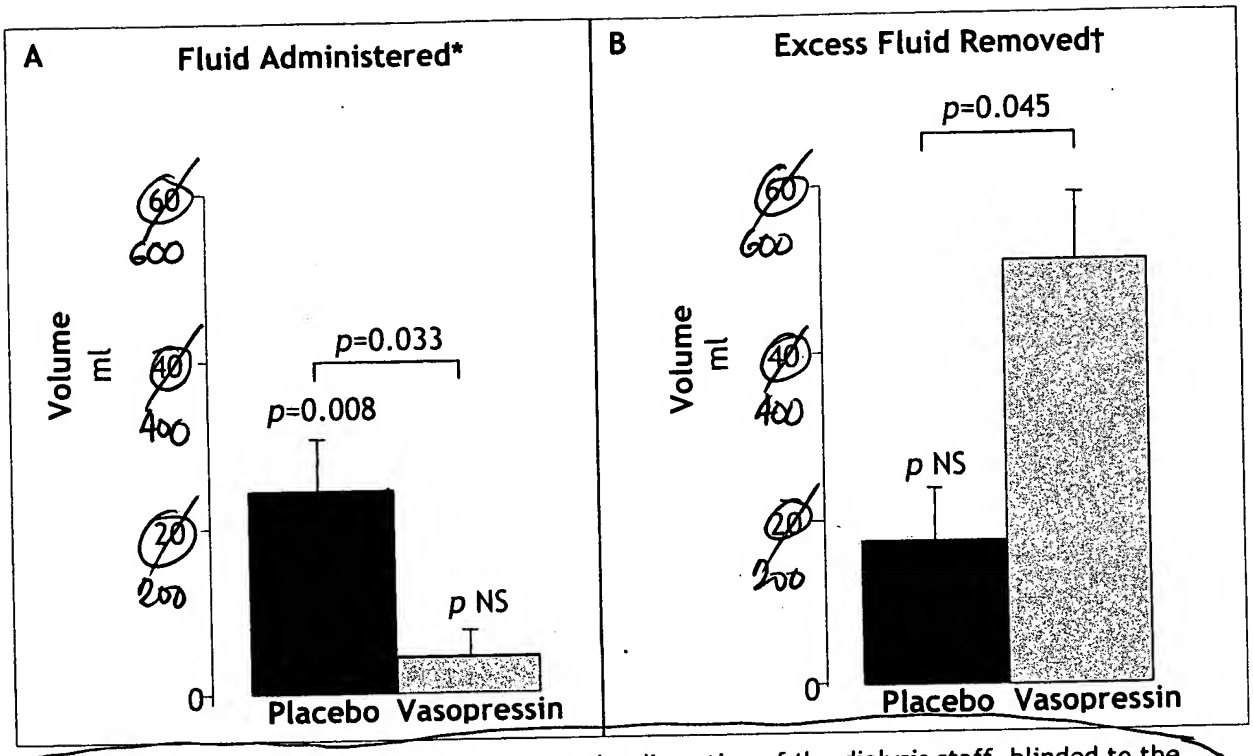
The weight gained since the last treatment (baseline prescription) and, therefore, the "Study target fluid loss" (baseline prescription plus 0.5 kg) did not differ between the two groups. Similarly, systolic arterial pressures before, during and after the dialysis were not significantly different between the two groups. However, systolic arterial pressure in the group of patients that received vasopressin was significantly more stable during the dialysis. In this group, when compared to the placebo group, the maximum drop from the overall systolic pressure was smaller (17±2 vs. 34±5 mm Hg, p=0.03) and the lowest systolic pressure was higher (130±7 vs. 114±5, p=0.02), indicating that vasopressin participated in arterial pressure maintenance as fluid was removed. In addition, increasing the target volume for fluid removal resulted in symptomatic hypotensive episodes in seven of the eleven patients receiving placebo but only one patient of eleven patients receiving vasopressin (63% vs. 9%, p=0.001).

In response to arterial pressure changes during dialysis, the nurse conducting the dialysis administered to patients in the placebo group 245±74 ml of normal saline for pressure support (p=0.008) but a non-significant amount of saline to those receiving vasopressin (40±43 ml; p=0.03 vs placebo; Figure 10A).

Finally, while the volume of extra fluid removed during the dialysis above the baseline prescription was not significant in the placebo group, (170±130 ml), patients receiving vasopressin attained the study's goal for additional fluid removal (460±100 ml; p<0.001; p=0.045 vs. placebo; Figure 10B). After the hemodialysis session, all patients were managed per routine. No patient reported orthostatic symptoms between the end of the study and the following dialysis.

Discussion

During hemodialysis, excess extracellular fluid is removed by ultrafiltration until the patient is returned to his or her "dry weight." However, "dry weight" is empirically assigned to that weight at which symptomatic decreases in blood pressure are very likely to occur if further volume is removed (Henderson, L. W. (1980). Kidney Int 17(5): 571-6;



* Fluid was administered for pressor support at the discretion of the dialysis staff, blinded to the study drug, on the basis of hypotensive episodes during dialysis.
† Excess fluid removed was defined as the difference between the baseline prescription weight loss and the actual weight loss achieved during the study hemodialysis.

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FIGURE 10

ANNOTATED MARKED-UP DRAWING